UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF ILLINOIS EAST ST. LOUIS DIVISION

ROBERT J. SMITH, JR., Individually and)
as Special Administrator of the Estate of) JURY TRIAL DEMANDED
ROBERT J. SMITH, SR.,	ON ALL COUNTS
Plaintiff,	
) Cause No. 3:06-cv-00964-DRH-CJP
MERCK & CO., INC., also d/b/a MERCK,	
SHARP AND DOHME and d/b/a	
MSD SHARP & DOHME GmbH,	
CVS EDWARDSVILLE IL, L.L.C.,)
d/b/a CVS PHARMACY,)
G.D. SEARLE LLC, PHARMACIA)
CORPORATION, MONSANTO)
COMPANY, PFIZER INC.,)
Defendants.	

MERCK & CO., INC.'S ANSWER AND DEFENSES TO PLAINTIFF'S COMPLAINT

COMES NOW Defendant Merck & Co., Inc. ("Merck"), improperly referred to by plaintiff as "Merck & Co., Inc., also d/b/a Merck, Sharp and Dohme and d/b/a MSD Sharp & Dohme GmbH," by and through its counsel, and presents the following Answer and Defenses to plaintiff's Complaint ("Complaint") as follows:

For the paragraphs numbered 1-62 of the Complaint, to the extent that these allegations are directed at Merck, Merck hereby responds as follows. To the extent that allegations contained in paragraphs 1-62 of the Complaint are directed at another party and not at Merck, no response is required and to the extent that it is deemed that a response is required from Merck, denies each and every allegation.

RESPONSE TO "THE PARTIES AS TO VIOXX"

- 1. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of paragraph 1 of the Complaint and demands strict proof thereof. Denies each and every allegation contained in the second sentence of paragraph 1 of the Complaint except admits that plaintiff purports to bring an action for certain personal injuries but denies that there is any legal or factual basis for same.
- 2. Denies each and every allegation contained in the first five sentences of paragraph 2 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx in a manner consistent with the information contained in the United States Food and Drug Administration ("FDA")-approved prescribing information for Vioxx and respectfully refers the Court to the relevant prescribing information for Vioxx's indicated uses. Merck further admits that Merck is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey. Merck admits the allegations contained in the sixth sentence of paragraph 2 of the Complaint.
- 3. Denies each and every allegation contained in paragraph 3 of the Complaint except admits that Merck manufactured, marketed, and distributed the prescription medicine Vioxx, until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and that Merck is authorized to conduct business in Illinois.
- 4. The allegations contained in paragraph 4 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed

required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 3 of the Complaint.

RESPONSE TO "DISCOVERY RULE AND FRAUDULENT CONCEALMENT"

- 5. Denies each and every allegation contained in paragraph 5 of the Complaint except admits that plaintiff purports to invoke the discovery rule to prevent his claim from being time barred but denies that there is any legal or factual basis for the same.
- 6. Denies each and every allegation contained in paragraph 6 of the Complaint.
- 7. Denies each and every allegation contained in the first sentence of paragraph 7 of the Complaint. The allegations contained in the second sentence of paragraph 7 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required. Merck denies each and every allegation contained in said sentence, and respectfully refers the Court to the relevant legal standard, including any conflict of laws rules. Merck denies each and every allegation set forth in the third sentence of paragraph 7 of the Complaint.
- 8. The allegations contained in paragraph 8 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in paragraph 8 of the Complaint except admits that plaintiff purports to invoke the discovery rule to prevent his claim from being time barred but denies that there is any legal or factual basis for the

same. Merck further admits that it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

RESPONSE TO "JURISDICTION AND VENUE"

- 9. The allegations contained in the first sentence of paragraph 9 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in the first sentence paragraph 9 of the Complaint. Merck denies each and every allegation contained in the second sentence of paragraph 9 of the Complaint.
- 10. Merck states that the allegations in paragraph 10 of the Complaint are legal conclusions as to which no response is required. Should a response be deemed required, Merck denies each and every allegation in paragraph 10 of the Complaint and avers that the United States District Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1332 and 1441.

RESPONSE TO "INTRODUCTION"

- 11. Denies each and every allegation contained in paragraph 11 of the Complaint except admits that Merck sought and, in 1999, received FDA approval to manufacture and market the prescription medicine Vioxx. Merck further admits that Vioxx is the brand name for rofecoxib.
- 12. Denies each and every allegation contained in paragraph 12 of the Complaint except admits that Merck manufactured, marketed, and distributed the

prescription medicine Vioxx, until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

- 13. Denies each and every allegation contained in paragraph 13 of the Complaint, except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx until it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and respectfully refers the Court to the FDA-approved prescribing information for Vioxx for its actual language and full text.
- 14. Denies each and every allegation contained in paragraph 14 of the Complaint except admits that Vioxx is part of a class of medications known as NSAIDs, that Merck manufactured, marketed, and distributed the prescription medicine Vioxx which reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2). Merck further avers that Vioxx has been proven in randomized clinical trials to reduce the rate of gastrointestinal injuries compared to Naproxen, which is a non-selective NSAID.
- 15. Denies each and every allegation contained in paragraph 15 of the Complaint except admits that Merck sought and, in 1999, received FDA approval to manufacture and market the prescription medicine Vioxx as safe and effective for certain indicated uses in a manner consistent with the relevant FDA-approved prescribing information. Merck respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its indicated uses and full text.

- 16. Lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first and second sentences of paragraph 16 of the Complaint, demands strict proof thereof, and in the alternative denies the same.

 Denies each and every allegation contained in the third sentence of paragraph 16 of the Complaint.
- 17. Denies each and every allegation contained in paragraph 17 of the Complaint.
- 18. Denies each and every allegation contained in paragraph 18 of the Complaint.
- 19. Denies each and every allegation contained in paragraph 19 of the Complaint.

RESPONSE TO "FACTS – VIOXX'S PRE-APPROVAL"

- 20. Merck denies each and every allegation in paragraph 20 of the Complaint.
- 21. Denies each and every allegation contained in paragraph 21 of the Complaint except admits that Plaintiff purports to quote a portion of a document, but Merck avers that said quoted language is taken out of context.
- 22. Denies each and every allegation set forth in paragraph 22 of the Complaint.

RESPONSE TO "FACTS – VIOXX'S POST-APPROVAL"

- 23. Denies each and every allegation contained in paragraph 23 of the Complaint.
- 24. Denies each and every allegation contained in paragraph 24 of the Complaint, except admits that Vioxx, like all prescription medications, has had certain reported adverse events associated with its use, which were described in the relevant FDA-approved prescribing information for Vioxx and respectfully refers the Court to the relevant prescribing information for Vioxx for its actual language and full text.
- 25. Denies each and every allegation contained in paragraph 25 of the Complaint.
- 26. Denies each and every allegation contained in paragraph 26 of the Complaint except admits that the VIGOR study involving Vioxx exists and respectfully refers the Court to the referenced study for its actual conclusions and full text. Merck further admits that it provided preliminary results of the VIGOR study to the FDA in March 2000.
- 27. Merck denies each and every allegation contained in paragraph 27 of the Complaint except admits that Plaintiff purports to quote the referenced email, but avers that any such statements are taken out of context.
- 28. Merck denies each and every allegation in paragraph 28 of the Complaint, except admits that the referenced press release exists, and respectfully refers the Court to the referenced document for its actual language and full text.
- 29. Denies each and every allegation set forth in paragraph 29 of the Complaint, except admits that Merck issued a press release on April 28, 2000 entitled:

"Merck Confirms Favorable Cardiovascular Profile of VIOXX" and respectfully refers the Court to the referenced press release for its actual language and full text.

- 30. Denies each and every allegation contained in paragraph 30 of the Complaint except admits that the studies referenced in sentence one of paragraph 30 and the article referenced in sentence two of paragraph 30 exist, and respectfully refers the Court to said publications for their actual language and full text. Merck further admits that it is currently a member of the European League Against Rheumatism ("EULAR") and that it has been a sponsor of EULAR since 1999.
- 31. Denies each and every allegation contained in paragraph 31 of the Complaint, except admits that 2000 worldwide Vioxx sales figures exceeded \$2 billion.
- 32. Denies each and every allegation contained in paragraph 32 of the Complaint.
- 33. Denies each and every allegation contained in paragraph 33 of the Complaint except admits that Plaintiff purports to quote a portion of the referenced letter but respectfully refers the Court to said letter for its actual language and full text.
- 34. Denies each and every allegation in paragraph 34 of the Complaint except admits that Plaintiffs appear to be quoting a portion of a piece of correspondence that Merck received from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.
- 35. Denies each and every allegation contained in paragraph 35 of the Complaint including subparagraphs (a)-(g) except admits that Plaintiffs purport to quote

portions of the referenced correspondence but avers that Plaintiffs have taken such language out of context and respectfully refers the Court to said letter for its actual language and full text.

- 36. Denies each and every allegation contained in paragraph 36 of the Complaint except admits that Plaintiff purports to quote portions of a certain document in said paragraph and Merck received a letter from Dr. Fries regarding Vioxx and that Plaintiff purports to quote portions of that letter, but Merck avers that any quoted language is taken out of context.
- 37. Merck denies each and every allegation directed at Merck in paragraph 37 of the Complaint. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in said paragraph.
- 38. Denies each and every allegation contained in the second paragraph 38 of the Complaint.
- 39. Merck denies each and every allegation set forth in paragraph 39 of the Complaint and avers that Merck marketed the prescription medicine Vioxx in a manner consistent with its FDA-approved prescribing information. Merck further admits that in 2001 Vioxx achieved sales of \$2.6 billion and that Vioxx was prescribed to millions of patients.
- 40. Merck denies each and every allegation in paragraph 40 of the Complaint except Merck admits that in April 2002 the FDA approved certain changes to the Vioxx

prescribing information and respectfully refers the Court to the prescribing information for Vioxx for its actual language and full text.

- 41. Denies each and every allegation contained in paragraph 41 of the Complaint except admits that Merck received a letter in September 2001 from Thomas W. Abrams of DDMAC and respectfully refers the Court to that letter for its actual language and full text.
- 42. Denies each and every allegation set forth in paragraph 42 of the Complaint except admits that the referenced publication and the article contained therein exist and respectfully refers the Court to the referenced document for its actual language and full text.
- 43. Denies each and every allegation set forth in the first two sentences of paragraph 43 of the Complaint except admits that the referenced journals and articles contained therein exist, and that Plaintiff purports to quote from the same and respectfully refers the Court to said studies for their actual language and full context. Denies each and every allegation in the third sentence of paragraph 43 of the Complaint except admits that the referenced journal and article exist and respectfully refers the Court to said article for its actual language and full context.
- 44. Denies each and every allegation contained in paragraph 44 of the Complaint.
- 45. Denies each and every allegation contained in paragraph 45 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of

DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

- 46. Denies each and every allegation contained in paragraph 46 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.
- 47. Denies each and every allegation contained in paragraph 47 of the Complaint except admits that Merck marketed Vioxx in a manner consistent with the relevant FDA-approved prescribing information.
- 48. Denies each and every allegation contained in paragraph 48 of the Complaint except admits that Merck trains its professional representatives.
- 49. Merck admits that in April 2002 the FDA approved certain changes to the Vioxx prescribing information and respectfully refers the Court to the relevant prescribing information for Vioxx for its actual language and full text. Merck denies each and every remaining allegation set forth in paragraph 49 of the Complaint.
- 50. Denies each and every allegation contained in paragraph 50 of the Complaint, except admits that the VALOR study was proposed as one of several options and that in a March 13, 2002 email the proposal was put on hold to explore other alternatives.
- 51. Merck denies each and every allegation set forth in the first three sentences of paragraph 51 of the Complaint except admits the existence of the referenced

article and respectfully refers the Court to said article for its actual language and full text. Merck denies each and every allegation set forth in the fourth sentence of paragraph 51 of the Complaint and avers that the referenced action against Dr. Laporte and the Catalan Institute of Pharmacology was commenced by a Merck subsidiary, MERCK SHARP & DOHME DE ESPAÑA, S.A. (MSD). Merck denies each and every allegation set forth in the fifth sentence of paragraph 51 of the Complaint and respectfully refers the Court to the referenced decision for its actual language and full context.

- 52. Denies each and every allegation contained in paragraph 52 of the Complaint except admits that the referenced article exists and respectfully refers the Court to the referenced publication for its actual language and full text. Merck denies each and every allegation in the fourth sentence of paragraph 52 except admits that Vioxx was registered, marketed and sold in approximately 80 countries outside the United States.
- 53. Denies each and every allegation set forth in paragraph 53 of the Complaint except admits that the presentation referenced in that paragraph exists, and respectfully refers the Court to the presentation for its actual language and full text.
- 54. Denies each and every allegation contained in paragraph 54 of the Complaint except admits the referenced press release exists and respectfully refers the Court to that press release for its actual language and full text.
- 55. Denies each and every allegation set forth in paragraph 55 of the Complaint, except admits that on September 23, 2004, Merck was informed that the External Safety Monitoring Board (ESMB) had recommended that the APPROVe study

be stopped when preliminary results showed a small increased risk of confirmed cardiovascular events beginning after 18 months of continuous treatment with Vioxx.

56. Denies each and every allegation contained in the paragraph 56 except admits that on September 30, 2004 Merck announced the voluntary worldwide withdrawal of Vioxx and respectfully refers the Court to the referenced announcement for its actual language and full text and that Vioxx was prescribed to millions of patients by health care providers, and that Vioxx was registered, marketed and sold in approximately 80 countries outside the United States.

RESPONSE TO "SUMMARY"

- 57. Merck denies each and every allegation contained in paragraph 57 of the Complaint.
- 58. Merck denies each and every allegation contained in paragraph 58 of the Complaint.
- 59. Merck denies each and every allegation contained in paragraph 59 of the Complaint.
- 60. Merck denies each and every allegation contained in paragraph 60 of the Complaint.
- Merck denies each and every allegation contained in paragraph 61 of the 61. Complaint except admits that Merck marketed Vioxx.
- 62. Merck denies each and every allegation relating to Merck or Vioxx in paragraph 62 of the Complaint except admits that plaintiff seeks compensation for damages but denies that there is any factual or legal basis for such relief.

RESPONSE TO "COUNT 1-COMMON LAW STRICT LIABILITY-AGAINST MERCK (WRONGFUL DEATH ACT)"

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- 63. With respect to the allegations contained in paragraph 63 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 64. Merck denies each and every allegation contained in paragraph 64 of the Complaint except admits that plaintiff purports to invoke the doctrine of strict liability, but denies that there is any legal or factual basis for the same.
- 65. Merck denies each and every allegation contained in paragraph 65 of the Complaint.
- 66. Merck denies each and every allegation contained in paragraph 66 of the Complaint.
- 67. Denies each and every allegation contained in said paragraph except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 68. As for the unnumbered prayer for relief under paragraph 67, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 2-COMMON LAW STRICT LIABILITY-AGAINST MERCK (SURVIVAL ACT)"

69. With respect to the allegations contained in paragraph 68 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and

statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.

- 70. Denies each and every allegation in paragraph 69 of the Complaint except admits that Merck manufactured and marketed the prescription medicine Vioxx.
 - 71. Denies each and every allegation in paragraph 70 of the Complaint.
- 72. Denies each and every allegation in paragraph 71 of the Complaint except admits that plaintiff purports to seek damages but denies that there is any legal or factual basis for the same.
- 73. Denies each and every allegation contained in paragraph 72 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 74. As for the unnumbered prayer for relief under paragraph 72, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 3- NEGLIGENCE AND GROSS NEGLIGENCE-AGAINST MERCK (WRONGFUL DEATH ACT)"

- 75. With respect to the allegations contained in paragraph 73 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 76. Merck denies each and every allegation contained in paragraph 74 of the Complaint.
- 77. Merck denies each and every allegation contained in paragraph 75 of the Complaint including subparagraphs (a) - (p).

- 78. Merck denies each and every allegation contained in paragraph 76 of the Complaint.
- 79. Denies each and every allegation contained in paragraph 77 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 80. As for the unnumbered prayer for relief under paragraph 77, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 4- NEGLIGENCE AND GROSS NEGLIGENCE-AGAINST MERCK (SURVIVAL ACT)"

- 81. With respect to the allegations contained in paragraph 78 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 82. Denies each and every allegation in paragraph 79 of the Complaint except admits that Merck manufactured and marketed the prescription medicine Vioxx.
 - 83. Denies each and every allegation in paragraph 80 of the Complaint.
- 84. Denies each and every allegation in paragraph 81 of the Complaint except admits that plaintiff purports to seek damages but denies that there is any legal or factual basis for the same.
- 85. Denies each and every allegation contained in paragraph 82 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.

86. As for the unnumbered prayer for relief under paragraph 82, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 5-NEGLIGENCE – SALE OF PRODUCT – AGAINST MERCK (WRONGFUL DEATH ACT"

- 87. With respect to the allegations contained in paragraph 83 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 88. Merck denies each and every allegation set forth in paragraph 84 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
- 89. The allegations contained in paragraph 85 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the court to the relevant legal standard, including any conflict of laws rules.
- 90. The allegations contained in paragraph 86 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the court to the relevant legal standard, including any conflict of laws rules.
- 91. Merck denies each and every allegation contained in paragraph 87 of the Complaint.

- 92. Merck denies each and every allegation contained in paragraph 88 of the Complaint.
- 93. Merck denies each and every allegation contained in paragraph 89 of the Complaint.
- 94. Denies each and every allegation contained in paragraph 90 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 95. As for the unnumbered prayer for relief under paragraph 90, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 6-NEGLIGENCE – SALE OF PRODUCT – AGAINST MERCK (SURVIVAL ACT"

- 96. With respect to the allegations contained in paragraph 91 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 97. Denies each and every allegation in paragraph 92 of the Complaint except admits that Merck manufactured and marketed the prescription medicine Vioxx.
 - 98. Denies each and every allegation in paragraph 93 of the Complaint.
- 99. Denies each and every allegation in paragraph 94 of the Complaint except admits that plaintiff purports to seek damages but denies that there is any legal or factual basis for the same.

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- 100. Denies each and every allegation contained in paragraph 95 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 101. As for the unnumbered prayer for relief under paragraph 95, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 7-BREACH OF WARRANTIES (EXPRESS AND IMPLIED) AGAINST MERCK (WRONGFUL DEATH ACT)"

- 102. With respect to the allegations contained in paragraph 96 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 103. Merck denies each and every allegation contained in paragraph 97 of the Complaint and respectfully refers the Court to the FDA-approved prescribing information for Vioxx for its actual language and full text.
- 104. Denies each and every allegation contained in paragraph 98 of the Complaint, including subparts (a) through (f).
- 105. Denies each and every allegation contained in paragraph 99 of theComplaint.
- 106. Merck denies each and every allegation set forth in paragraph 100 of the Complaint and avers that it marketed Vioxx as safe and effective for certain indicated uses is a manner consistent with the information set forth in the relevant FDA-approved prescribing information for Vioxx, and respectfully refers the Court to the relevant prescribing information for Vioxx for its actual language and full text.

- 107. Denies each and every allegation contained in paragraph 101 of the Complaint.
- 108. Denies each and every allegation contained in paragraph 102 of the Complaint.
- 109. Denies each and every allegation contained in paragraph 103, including subparts (A) through (C), of the Complaint.
- Denies each and every allegation contained in paragraph 104 of the 110. Complaint.
- 111. Denies each and every allegation contained in paragraph 105 of the Complaint.
- 112. Denies each and every allegation contained in paragraph 106 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 113. As for the unnumbered prayer for relief under paragraph 106, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 8-BREACH OF WARRANTIES (EXPRESS AND IMPLIED) AGAINST MERCK (SURVIVAL ACT)"

- 114. With respect to the allegations contained in paragraph 107 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 115. Denies each and every allegation in paragraph 108 of the Complaint except admits that Merck manufactured and marketed the prescription medicine Vioxx.

116. Denies each and every allegation in paragraph 109 of the Complaint.

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- 117. Denies each and every allegation in paragraph 110 of the Complaint except admits that plaintiff purports to seek damages but denies that there is any legal or factual basis for the same.
- 118. Denies each and every allegation contained in paragraph 111 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 119. As for the unnumbered prayer for relief under paragraph 111, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 9 COMMON LAW FRAUD-AGAINST MERCK (WRONGFUL DEATH ACT)"

- 120. With respect to the allegations contained in paragraph 112 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 121. Denies each and every allegation contained in paragraph 113 of the Complaint.
- 122. Denies each and every allegation contained in paragraph 114 of the Complaint.
- 123. Denies each and every allegation contained in paragraph 115 of the Complaint.
- 124. Merck denies each and every allegation directed at Merck that is contained in paragraph 116 of the Complaint.

- 125. Denies each and every allegation contained in paragraph 117 of the Complaint.
- 126. Denies each and every allegation contained in paragraph 118 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 127. As for the unnumbered prayer for relief under paragraph 118, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 10 COMMON LAW FRAUD-AGAINST MERCK (SURVIVAL ACT)"

- 128. With respect to the allegations contained in paragraph 119 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- Denies each and every allegation in paragraph 120 of the Complaint 129. except admits that Merck manufactured and marketed the prescription medicine Vioxx.
 - 130. Denies each and every allegation in paragraph 121 of the Complaint.
- Denies each and every allegation in paragraph 122 of the Complaint 131. except admits that plaintiff purports to seek damages but denies that there is any legal or factual basis for the same.
- 132. Denies each and every allegation contained in paragraph 123 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.

133. As for the unnumbered prayer for relief under paragraph 123, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 11-NEGLIGENT MISREPRESENTATION-AGAINST MERCK (WRONGFUL DEATH ACT)"

- 134. With respect to the allegations contained in paragraph 124 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- Denies each and every allegation contained in paragraph 125 of the 135. Complaint.
- 136. Denies each and every allegation contained in paragraph 126 of the Complaint.
- Denies each and every allegation directed at Merck that is contained in 137. paragraph 127 of the Complaint.
- 138. The allegations contained in paragraph 128 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.
- 139. Denies each and every allegation contained in paragraph 129 of the Complaint.
- Denies each and every allegation contained in paragraph 130 of the 140. Complaint.
- Denies each and every allegation contained in paragraph 131 of the 141. Complaint.

- 142. Denies each and every allegation contained in paragraph 132 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 143. As for the unnumbered prayer for relief under paragraph 132, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 12-NEGLIGENT MISREPRESENTATION-AGAINST MERCK (SURVIVAL ACT)"

- 144. With respect to the allegations contained in paragraph 133 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- Denies each and every allegation in paragraph 134 of the Complaint 145. except admits that Merck manufactured and marketed the prescription medicine Vioxx.
 - 146. Denies each and every allegation in paragraph 135 of the Complaint.
- 147. Denies each and every allegation in paragraph 136 of the Complaint except admits that plaintiff purports to seek damages but denies that there is any legal or factual basis for the same.
- 148. Denies each and every allegation contained in paragraph 137 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 149. As for the unnumbered prayer for relief under paragraph 137, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 13-DECEPTIVE TRADE PRACTICES ACT-AGAINST MERCK (WRONGFUL DEATH ACT)"

- 150. With respect to the allegations contained in paragraph 138 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 151. The allegations contained in paragraph 139 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required. Merck denies each and every allegation contained in said paragraph except admits that plaintiff purports to bring the referenced action but denies that there is any legal or factual basis for same.
- 152. The allegations contained in paragraph 140 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph except admits that plaintiff purports to reference and characterize 815 ILCS 505 and respectfully refers the Court to the statute for its actual language and full text.
- 153. Denies each and every allegation contained in paragraph 141 of the Complaint.
- 154. Denies each and every allegation set forth in paragraph 142 of the Complaint, except admits that Merck trains its professional representatives.
- 155. Denies each and every allegation contained in paragraph 143 of the Complaint.

- 156. Denies each and every allegation contained in paragraph 144 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- As for the unnumbered prayer for relief under paragraph 144, no 157. responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "COUNT 14-DECEPTIVE TRADE PRACTICES ACT-AGAINST MERCK (SURVIVAL ACT)"

- 158. With respect to the allegations contained in paragraph 145 of the Complaint, repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 159. Denies each and every allegation in paragraph 146 of the Complaint except admits that Merck manufactured and marketed the prescription medicine Vioxx.
 - 160. Denies each and every allegation in paragraph 147 of the Complaint.
- 161. Denies each and every allegation in paragraph 148 of the Complaint except admits that plaintiff purports to seek damages but denies that there is any legal or factual basis for the same.
- 162. Denies each and every allegation contained in paragraph 149 of the Complaint except admits that plaintiff purports to bring a claim under the referenced statute but denies that there is any legal or factual basis for same.
- 163. As for the unnumbered prayer for relief under paragraph 149, no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this unnumbered prayer for relief.

RESPONSE TO "PARTIES AS TO CELEBREX"

164. The allegations contained in paragraphs 150-155 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "BACKGROUND-CELEBREX"

165. The allegations contained in paragraphs 156-163 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "JURIDICTION AND VENUE-CELEBREX"

The allegations contained in paragraphs 164-167 of the Complaint are not 166. directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 15 – STRICT PRODUCTS LIABILITY / DEFECTIVE **DESIGN - CELEBREX (WRONGFUL DEATH)"**

The allegations contained in paragraphs 168-175 of the Complaint are not 167. directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 16 - STRICT PRODUCTS LIABILITY / DEFECTIVE **DESIGN – CELEBREX (SURVIVAL ACT)"**

168. The allegations contained in paragraphs 176-180 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 17 – STRICT PRODUCTS LIABILITY / FAILURE TO WARN - CELEBREX (WRONGFUL DEATH)"

RESPONSE TO "COUNT 18 – STRICT PRODUCTS LIABILITY / FAILURE TO WARN – CELEBREX (SURVIVAL ACT)"

170. The allegations contained in paragraphs 193-197 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 19 – NEGLIGENT DESIGN – CELEBREX (WRONGFUL DEATH)"

171. The allegations contained in paragraphs 198-206 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 20 – NEGLIGENT DESIGN – CELEBREX (SURVIVAL ACT)"

172. The allegations contained in paragraphs 207-211 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 21 – NEGLIGENT FAILURE TO WARN – CELEBREX (WRONGFUL DEATH)"

173. The allegations contained in paragraphs 212-218 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 22 – NEGLIGENT FAILURE TO WARN – CELEBREX (SURVIVAL ACT)"

RESPONSE TO "COUNT 23 – FRAUDULENT CONCEALMENT – CELEBREX (WRONGFUL DEATH)"

deemed required, Merck denies each and every allegation contained is said paragraphs.

175. The allegations contained in paragraphs 224-239 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 24 – FRAUDULENT CONCEALMENT – CELEBREX (SURVIVAL ACT)"

176. The allegations contained in paragraphs 240-244 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 25 – COMMON LAW FRAUD – CELEBREX (WRONGFUL DEATH)"

177. The allegations contained in paragraphs 245-252 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 26 – COMMON LAW FRAUD – CELEBREX (SURVIVAL ACT)"

178. The allegations contained in paragraphs 253-257 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 27 – BREACH OF IMPLIED WARRANTY – CELEBREX (WRONGFUL DEATH)"

179. The allegations contained in paragraphs 258-265 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 28 – BREACH OF IMPLIED WARRANTY – CELEBREX (SURVIVAL ACT)"

180. The allegations contained in paragraphs 266-270 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 29 – BREACH OF EXPRESS WARRANTY – CELEBREX (WRONGFUL DEATH)"

181. The allegations contained in paragraphs 271-278 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 30 - BREACH OF EXPRESS WARRANTY -CELEBREX (SURVIVAL ACT)"

182. The allegations contained in paragraphs 279-283 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 31 – NEGLIGENT MISREPRESENTATION – CELEBREX (WRONGFUL DEATH)"

183. The allegations contained in paragraphs 284-294 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 32 – NEGLIGENT MISREPRESENTATION – **CELEBREX (SURVIVAL ACT)"**

184. The allegations contained in paragraphs 295-299 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 33 – STRICT PRODUCTS LIABILITY / SALE OF DEFECTIVE PRODUCT – AGAINST CVS (WRONGFUL DEATH ACT)"

185. The allegations contained in paragraphs 300-304 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 34 – STRICT PRODUCTS LIABILITY / SALE OF DEFECTIVE PRODUCT – AGAINST CVS (SURVIVAL ACT)"

186. The allegations contained in paragraphs 305-309 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 35 – NEGLIGENCE, FAILURE TO WARN – AGAINST CVS (WRONGFUL DEATH ACT)"

187. The allegations contained in paragraphs 310-315 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 36 – NEGLIGENCE, FAILURE TO WARN – AGAINST CVS (SURVIVAL ACT)"

188. The allegations contained in paragraphs 316-320 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 37 – BREACH OF WARRANTY – AGAINST CVS (WRONGFUL DEATH ACT)"

189. The allegations contained in paragraphs 321-326 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 38 – BREACH OF WARRANTY – AGAINST CVS (SURVIVAL ACT)"

190. The allegations contained in paragraphs 327-331 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained is said paragraphs.

RESPONSE TO "COUNT 39 – LOSS OF CONSORTIUM AS TO MERCK, G.D. SEARLE LLC, PHARMACIA CORPORATION, MONSANTO COMPANY AND PFIZER, INC. AND CVS

- 191. Lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 332 of the Complaint.
- 192. Lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 333 of the Complaint.
- 193. Denies each and every allegation contained in paragraph 334 of the Complaint.

RESPONSE TO "PRAYER FOR RELIEF AS TO ALL COUNTS"

194. As for the "prayer for relief," including subparagraphs (a)-(e), no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in this prayer for relief, including subparagraphs (a)-(e).

JURY DEMAND

Merck hereby requests a trial by jury.

DEFENSES

For its defenses to plaintiff's Complaint, Defendant Merck & Co., Inc. states as follows:

AS FOR A FIRST DEFENSE, **MERCK ALLEGES:**

195. Each and every claim asserted or raised in the Complaint is barred by the applicable statutes of limitations and is otherwise untimely.

AS FOR A SECOND DEFENSE, **MERCK ALLEGES:**

196. The Complaint fails to state a claim upon which relief can be granted.

AS FOR A THIRD DEFENSE, **MERCK ALLEGES:**

The claims of the Plaintiff may be barred, in whole or in part, from 197. recovery because he has made statements or taken actions that preclude him from asserting claims or constitute a waiver of his claims.

AS FOR A FOURTH DEFENSE, **MERCK ALLEGES:**

198. The claims of the Plaintiff may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

AS FOR A FIFTH DEFENSE, **MERCK ALLEGES:**

199. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

AS FOR A SIXTH DEFENSE, **MERCK ALLEGES:**

200. If plaintiff or plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were cause in whole or in part through the operation of nature or other intervening cause or causes.

AS FOR A SEVENTH DEFENSE, **MERCK ALLEGES:**

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201. To the extent that plaintiff asserts claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

AS FOR AN EIGHTH DEFENSE, **MERCK ALLEGES:**

202. To the extent that plaintiff asserts claims based upon an alleged failure by Merck to warn plaintiff's decedent directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

AS FOR A NINTH DEFENSE, **MERCK ALLEGES:**

203. Any warnings given by Merck were transmitted to the prescribing physicians and/or healthcare providers and, pursuant to the learned intermediary doctrine, Merck's only obligation is to warn the prescribing physician and/or healthcare providers and said obligation was fulfilled.

AS FOR A TENTH DEFENSE, **MERCK ALLEGES:**

204. If plaintiff or plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured plaintiff's decedent.

AS FOR A ELEVENTH DEFENSE, **MERCK ALLEGES:**

205. Any liability that might otherwise be imposed upon this defendant is subject to reduction by the application of the doctrine of comparative negligence.

AS FOR A TWELFTH DEFENSE, **MERCK ALLEGES:**

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206. If plaintiff or plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after plaintiff's decedent knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

AS FOR AN THIRTEENTH DEFENSE, **MERCK ALLEGES:**

207. If plaintiff or plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

AS FOR A FOURTEENTH DEFENSE, **MERCK ALLEGES:**

208. If plaintiff or plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by plaintiff's decedent's misuse or abuse of Vioxx.

AS FOR A FIFTEENTH DEFENSE, **MERCK ALLEGES:**

209. If plaintiff or plaintiff's decedent has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from plaintiff's decedent's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses,

subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

AS FOR A SIXTEENTH DEFENSE, **MERCK ALLEGES:**

210. To the extent plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

AS FOR A SEVENTEENTH DEFENSE, **MERCK ALLEGES:**

211. To the extent plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

AS FOR AN EIGHTEENTH DEFENSE, **MERCK ALLEGES:**

212. Plaintiff's claims of fraud are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Federal Rule of Civil Procedure 9(b).

AS FOR A NINETEENTH DEFENSE, **MERCK ALLEGES:**

213. Plaintiff's claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

AS FOR A TWENTIETH DEFENSE, **MERCK ALLEGES:**

214. Plaintiff's claims are barred in whole or in part by the First Amendment.

AS FOR A TWENTY-FIRST DEFENSE, MERCK ALLEGES:

215. Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

AS FOR A TWENTY-SECOND DEFENSE, <u>MERCK ALLEGES:</u>

216. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

AS FOR A TWENTY- THIRD DEFENSE, MERCK ALLEGES:

217. This case is more appropriately brought in a different venue.

AS FOR A TWENTY- FOURTH DEFENSE, MERCK ALLEGES:

218. Venue in this case is improper.

AS FOR A TWENTY- FIFTH DEFENSE, MERCK ALLEGES:

219. The claims of Plaintiff may be barred, in whole or in part, from recovery because, in this or other courts, he has brought actions and has received judgments on parts of some or all claims asserted herein.

AS FOR A TWENTY- SIXTH DEFENSE, MERCK ALLEGES:

220. The claims of Plaintiff may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

AS FOR A TWENTY- SEVENTH DEFENSE, MERCK ALLEGES:

221. The claims of Plaintiff may be barred, in whole or in part, from recovery by release as to their claims.

AS FOR A TWENTY- EIGHTH DEFENSE, MERCK ALLEGES:

222. The claims of Plaintiff may be barred, in whole and in part, pursuant to the doctrine of accord and satisfaction.

AS FOR A TWENTY-NINTH DEFENSE, <u>MERCK ALLEGES:</u>

223. The claims of Plaintiff may be barred, in whole and in part, by the doctrine of laches.

AS FOR A THIRTIETH DEFENSE, MERCK ALLEGES:

224. The claims of Plaintiff are barred, in whole or in part, by his failure to mitigate damages.

AS FOR A THIRTY-FIRST DEFENSE, MERCK ALLEGES:

225. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and

AS FOR A THIRTY-SECOND DEFENSE, MERCK ALLEGES:

226. The claims of Plaintiff may be time-barred, in whole or in part, under applicable statutes of limitations or statutes of repose.

AS FOR A THIRTY-THIRD DEFENSE, MERCK ALLEGES:

227. The claims of Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence.

AS FOR A THIRTY-FOURTH DEFENSE, MERCK ALLEGES:

228. The claims of Plaintiff may be barred, in whole or in part, by the governing state laws.

AS FOR A THIRTY-FIFTH DEFENSE, MERCK ALLEGES:

229. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

AS FOR A THIRTY-SIXTH DEFENSE, MERCK ALLEGES:

230. Plaintiff has not sustained any injury or damages compensable at law.

AS FOR A THIRTY-SEVENTH DEFENSE, <u>MERCK ALLEGES:</u>

Merck reserves its right to dismiss the Complaint and seek further relief 231. for Plaintiff's failure to provide it with due process of law.

AS FOR A THIRTY-EIGHTH DEFENSE, **MERCK ALLEGES:**

232. Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

AS FOR A THIRTY-NINTH DEFENSE, **MERCK ALLEGES:**

Plaintiff's claims are barred in whole or in part because Merck provided 233. adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiff alleges to have been taken by plaintiff's decedent within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

AS FOR A FORTIETH DEFENSE, **MERCK ALLEGES:**

234. Plaintiff's claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

AS FOR A FORTY-FIRST DEFENSE, **MERCK ALLEGES:**

235. Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

AS FOR A FORTY-SECOND DEFENSE, **MERCK ALLEGES:**

236. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal,

contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery in this action.

AS FOR A FORTY-THIRD DEFENSE, MERCK ALLEGES:

237. If plaintiff or plaintiff's decedent sustained the injuries or incurred the expenses alleged, the same were caused, in whole or in part, by operation of nature or an act of God.

AS FOR A FORTY-FOURTH DEFENSE, MERCK ALLEGES:

238. If plaintiff or plaintiff's decedent sustained the injuries or incurred the expenses alleged, the same were caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of Merck.

AS FOR A FORTY-FIFTH DEFENSE, MERCK ALLEGES:

239. The injuries and damages alleged in plaintiff's Complaint were the result of unavoidable circumstances that could not have been prevented by anyone, including Merck.

AS FOR A FORTY-SIXTH DEFENSE, MERCK ALLEGES:

240. The benefits of the product or products at issue outweigh the risks, if any, which may be attendant to their use.

AS FOR A FORTY-SEVENTH DEFENSE, MERCK ALLEGES:

241. Merck has complied with all requirements of the Food and Drug

Administration of the United States Department of Health and Human Services, and the

product or products at issue were approved pursuant to the applicable statutes and regulations. Pursuant to such, the product or products at issue could only be used pursuant to the prescription of a licensed prescriber. The package insert for the product or products at issue was also approved by the Food and Drug Administration, and the marketing was conducted in conformity with the regulations of the Food and Drug Administration. Therefore, plaintiff's claims are preempted.

AS FOR A FORTY-EIGHTH DEFENSE, MERCK ALLEGES:

242. The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

AS FOR A FORTY-NINTH DEFENSE, MERCK ALLEGES:

243. Merck made no express or implied representations or warranties of any kind to plaintiff or plaintiff's decedent, nor did plaintiff or plaintiff's decedent rely on any representations or warranties made by Merck. To the extent plaintiff or plaintiff's decedent relied upon any representations or warranties, such reliance was unjustified.

AS FOR A FIFTIETH DEFENSE, MERCK ALLEGES:

244. Merck did not breach any duty of care to plaintiff or plaintiff's decedent.

AS FOR A FIFTY-FIRST DEFENSE, <u>MERCK ALLEGES:</u>

245. Plaintiff has failed to join all necessary and indispensable parties.

AS FOR A FIFTY-SECOND DEFENSE, MERCK ALLEGES:

246. Merck did not violate any state or federal statute, regulation or ordinance to cause plaintiff's alleged injuries.

AS FOR A FIFTY-THIRD DEFENSE, <u>MERCK ALLEGES:</u>

247. A plaintiff who experienced no manifestation of the alleged defect has no claim against defendant upon which relief may be granted.

AS FOR A FIFTY-FOURTH DEFENSE, MERCK ALLEGES:

248. Merck lacked the requisite scienter and did not consciously or deliberately engage in or perpetuate any fraud with respect to the plaintiff or plaintiff's decedent.

AS FOR A FIFTY-FIFTH DEFENSE, <u>MERCK ALLEGES:</u>

249. Plaintiff lacks standing to assert claims under the Illinois Consumer Fraud and Deceptive Business Practices Act or any Illinois consumer protection statute.

AS FOR A FIFTY-SIXTH DEFENSE, MERCK ALLEGES:

250. Section 10b(1) of the Consumer Fraud Act provides that the Consumer Fraud Act does not apply to "[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." (Ill.Rev.Stat.1981, ch. 121 1/2, par. 270b(1).) Under this provision, conduct which is authorized by Federal statutes and regulations is exempt from liability under the Consumer Fraud Act. Lanier v. Associates Finance, Inc., 114 Ill.2d 1, *17, 499 N.E.2d 440, **447, 101 Ill.Dec. 852, ***859 (Ill.,1986).

AS FOR A FIFTY-SEVENTH DEFENSE, MERCK ALLEGES:

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251. Plaintiff may be barred from bringing an action pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act because the actions or transactions at issue were authorized by laws administered by a regulatory body or officer acting under statutory authority of the United States. 815 ILCS 505/10b(1).

AS FOR A FIFTY-EIGHTH DEFENSE, MERCK ALLEGES:

252. Defendant CVS is improperly joined.

AS FOR A FIFTY-NINTH DEFENSE, MERCK ALLEGES:

253. To the extent that plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity and/or because the alleged warranties were disclaimed.

AS FOR A SIXTIETH DEFENSE, MERCK ALLEGES:

254. Plaintiff's claims for negligence per se are barred on the grounds that such claims are not cognizable against Merck in this action.

AS FOR A SIXTY-FIRST DEFENSE, <u>MERCK ALLEGES:</u>

255. Plaintiffs' claims are barred, in whole or in part, because plaintiffs lack capacity and/or standing to bring such claims.

AS FOR A SIXTY-SECOND DEFENSE, MERCK ALLEGES:

265. To the extent that plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

AS FOR A SIXTY-THIRD DEFENSE,

MERCK ALLEGES:

266. To the extent that plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages is barred.

AS FOR A SIXTY-FOURTH DEFENSE, MERCK ALLEGES:

267. Plaintiffs' demand for punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

AS FOR A SIXTY-FIFTH DEFENSE, MERCK ALLEGES:

268. Plaintiffs fail to allege facts from which it can reasonably inferred to the level of clear and convincing proof that defendant acted with complete indifference to or conscious disregard for the safety of others.

AS FOR A SIXTY-SIXTH DEFENSE, <u>MERCK ALLEGES:</u>

269. Plaintiffs should not be afforded the right to a jury trial on their claim for punitive damages.

AS FOR A SIXTY-SEVENTH DEFENSE, MERCK ALLEGES:

270. Plaintiffs are not entitled to recover exemplary or punitive damages because the standards and procedures for determining and reviewing such awards under applicable law do not sufficiently ensure a meaningful individualized assessment of appropriate deterrence and retribution.

AS FOR A SIXTY-EIGHTH DEFENSE, MERCK ALLEGES:

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271. Plaintiffs are not entitled to recover exemplary or punitive damages because exemplary or punitive damages in this case would result in a violation of the due process clause of the Fourteenth Amendment of the United States Constitution and the Illinois Constitution as set forth in State Farm Mutual Automobile Insurance Co. v. Campbell, 123 S.Ct. 1513 (2003).

AS FOR A SIXTY-NINTH DEFENSE, **MERCK ALLEGES:**

272. Plaintiffs are not entitled to recover exemplary or punitive damages because exemplary or punitive damages in this case would result in a violation of Merck's constitutional protection and the prohibitions against double jeopardy set forth in the Fifth Amendment and the due process clause of the Fourteenth Amendment of the United States Constitution and comparable provisions of the Illinois Constitution.

AS FOR A SEVENTIETH DEFENSE, **MERCK ALLEGES:**

Plaintiffs are not entitled to recover exemplary or punitive damages 273. because exemplary or punitive damages in this case would result in an unconstitutionally excessive fine in violation of the Eighth Amendment and the Due Process Clause of the Fourteenth Amendment of the United States Constitution and comparable provisions of the Illinois Constitution.

AS FOR A SEVENTY-FIRST DEFENSE, **MERCK ALLEGES:**

274. Plaintiffs are not entitled to recover exemplary or punitive damages because exemplary or punitive damages in this case would result in a violation of the prohibition against ex post facto laws and laws impairing the obligations of contracts

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contained in Sections 9 and 10 of Article I of the United States Constitution and comparable provisions of the Illinois Constitution.

AS FOR A SEVENTY-SECOND DEFENSE, **MERCK ALLEGES:**

275. Plaintiffs are not entitled to recover exemplary or punitive damages because plaintiffs' claim for exemplary or punitive damages is in violation of the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Illinois Constitution because there are not realistic standards or limits imposed on the amount of punitive damages which may be awarded, and no required relationship between the actual damages sustained and the amount of punitive damages which may be awarded.

AS FOR A SEVENTY-THIRD DEFENSE, **MERCK ALLEGES:**

Plaintiffs are not entitled to recover exemplary or punitive damages 276. because plaintiffs' claim for exemplary or punitive damages is in violation of the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Illinois Constitution because the vague standards employed in punitive damage cases results in extremely disparate results among similar defendants accused of similar conduct.

AS FOR A SEVENTY-FOURTH DEFENSE, **MERCK ALLEGES:**

277. Plaintiffs are not entitled to recover exemplary or punitive damages because plaintiffs' claim for exemplary or punitive damages is in violation of the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Illinois Constitution because the purpose

AS FOR A SEVENTY-FIFTH DEFENSE, MERCK ALLEGES:

278. Plaintiffs are not entitled to recover exemplary or punitive damages because plaintiffs' claim for exemplary or punitive damages is in violation of the First Amendment to the United States Constitution and comparable provisions of the Illinois Constitution.

AS FOR A SEVENTY-SIXTH DEFENSE, MERCK ALLEGES:

279. Plaintiffs are not entitled to recover exemplary or punitive damages because the standards and instructions regarding exemplary/punitive damages are inadequate, vague, and ambiguous, further violating the Due Process Clause of the Fourteenth Amendment of the United States Constitution and the Illinois Constitution.

AS FOR A SEVENTY-SEVENTH DEFENSE, <u>MERCK ALLEGES:</u>

280. Merck avers that any award of punitive damages to the plaintiffs in this case will be violative of the procedural safeguards provided to defendants under the Sixth Amendment to the Constitution of the United States in that punitive damages are penal in nature and, consequently, Merck is entitled to the same procedural safeguards accorded to criminal defendants.

AS FOR A SEVENTY-EIGHTH DEFENSE, MERCK ALLEGES:

281. The correct standard for submitting the burden of proof for exemplary and/or punitive damages is "clear and convincing" evidence. Any lesser standard is a violation of the Due Process Clause of the Fourteenth Amendment of the United States Constitution and the Illinois Constitution.

AS FOR A SEVENTY-NINTH DEFENSE, MERCK ALLEGES:

282. Plaintiffs are not entitled to recover exemplary or punitive damages because the imposition of exemplary or punitive damages in this case based upon evidence of Merck's wealth or financial status would violate the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Illinois Constitution.

AS FOR A EIGHTIETH DEFENSE, MERCK ALLEGES:

283. Merck incorporates any applicable affirmative defense or other defense asserted by any other defendant in this action. Merck will rely on all defenses that may become available during discovery or trial.

CONCLUSION

WHEREFORE, PREMISES CONSIDERED, Defendant Merck & Co., Inc. respectfully requests that plaintiff take nothing in this suit, that it recover its costs of court and expenses and such other relief to which it may show itself justly entitled.

Respectfully submitted,

BRYAN CAVE LLP

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Attorneys for Merck & Co., Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 22, 2006, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system upon all counsel of record.

/s/ Randy J. Soriano